IN THE UNITED STATES DISTRICT COURT FOR THE WESTERN DISTRICT OF NORTH CAROLINA

GINA NEIL,

Plaintiff

vs. **Case No: _____**

CARTIVA, INC., WRIGHT MEDICAL GROUP, N.V., and STRYKER B.V.

Defendants

COMPLAINT

COMES NOW, the Plaintiff, GINA NEIL for her claims for relief against the Defendants, Cartiva, Inc., Wright Medical Group, N.V., and Stryker, B.V. f/ka Wright Medical Group ("Wright") f/k/a Cartiva, Inc., and alleges and states as follows:

I. JURISDICTION

1. Plaintiff is and at all times relevant to this action, was a citizen and resident of the State of North Carolina with her place of residence being 681 Berrys Branch Road, Millers Creek, North Carolina 28651.

2. Defendant Cartiva, Inc. is, and at all times relevant to this action, was a corporation with its principal place of business and headquarters located at 6120 Windward Parkway, Suite 220, Alpharetta, Georgia 30005 and process may be served upon its registered agent, CT Corporation System, 289 South Culver Street, Lawrenceville, Georgia 30046-4805

3. Defendant Wright Medical Group, N.V. is, and at all times relevant to this action, was a corporation with its principal place of business and headquarters located at 1023 Cherry Road, Memphis, Tennessee 38117 and process may be served upon its registered agent, CT Corporation System, 300 Montvue Road, Knoxville, Tennessee 37919-5546.

4. Defendant Stryker, B.V., is, and at all times relevant to this action, was a corporation with its principal place of business and headquarters located at 2825 Airview Boulevard, Kalamazoo, Michigan 49002.

5. At all times material hereto, Defendants Stryker, B.V., Wright Medical Group, N.V and Cartiva, Inc. (hereinafter referred to collectively as "Defendants") developed, tested, assembled, manufactured, packaged, labeled, prepared, distributed, marketed, supplied, and/or sold the defective product sold under the name "Cartiva SCI" (hereinafter "Cartiva" or "Defective Device"), either directly or indirectly, to members of the general public within the State of California, including Plaintiff.

6. Defendants' Defective Device was placed into the stream of interstate commerce and was implanted in Plaintiff on November 10, 2017 at The William B. Mulherin Surgery Center in Athens, Georgia by Joseph Johnson, M.D.

7. On June 13, 2019, Plaintiff underwent a Reference Total Toe Replacement with bone void filler of the right great toe, removal of Lapidus hardware, burial of midline right dorsal nerve at Resurgens in Kennesaw, Georgia by Errol Bailey, M.D.

8. As a direct and proximate result of Defendants placing the Defective Product into the stream of commerce, Plaintiff has suffered and continues to suffer both injuries and damages within the State of North Carolina, including but not limited to: past, present and future physical and mental pain and suffering; and past, present and future medical, hospital, monitoring, rehabilitative and pharmaceutical expenses and lost wages.

9. Upon information and belief, at all relevant times, Defendants were present and transacted, solicited and conducted business in the State of North Carolina through their

employees, agents and/or sales representatives, and derived substantial revenue from such business.

10. Defendants are conclusively presumed to have been doing business in this state and are subject to North Carolina's long arm jurisdiction.

11. At all relevant times, Defendants expected or should have expected that their acts and omissions would have consequences within the United States and the State of North Carolina.

12. Venue is proper in this Court because Plaintiff resides in Wilkes County, North Carolina.

II. GENERAL ALLEGATIONS

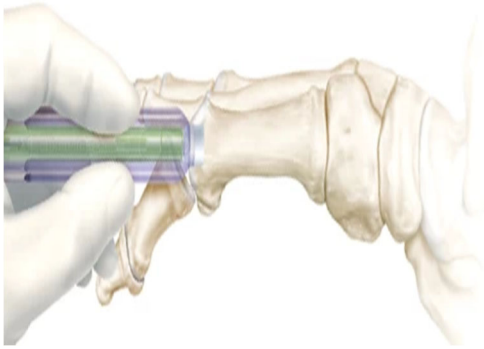
13. This is a products liability action arising out of Defendants, Cartiva, Inc., Wright Medical Group, NV, and Stryker, BV f/k/a Wright Medical Group f/k/a Cartiva, Inc. (hereinafter "Defendants") violations of various sections of the Federal Code of Regulations and the damages suffered by Plaintiff as a result thereof.

14. Big toe arthritis affects about 2.2 million in the U.S. As the arthritis deteriorates the joint's cartilage a person develops an extremely painful bone-on-bone painful rubbing of the bones. This condition can be surgically treated with 1) Arthrodesis a/k/a "fusion" or 2) a Cartiva® SCI (Synthetic Cartilage Implant hereinafter referred to as "Cartiva" or "defective device") implant, which acts like a cushion to prevent the bone-on-bone pain.

A. Cartiva Implant Treatment Option

15. The Cartiva implant is a molded cylindrical implant that is placed into the metatarsal head in the first metatarsophalangeal joint via press-fit implantation using instruments specifically designed for placement of the device.[1]

[1] Home > For Physicians > Implant Procedure(https://www.cartiva.net) (https://www.cartiva.net/for-physicians/)



Press Fit Application of Cartiva Implant

16. Defendants tout Cartiva as a simple procedure, which enables surgeons to replace the damaged cartilage with a bullet-sized implant they can place into an intraoperatively created pilot hole in the first metatarsal head.

17. The Cartiva implant is used in the treatment of patients with painful degenerative or post-traumatic arthritis (hallux limitus or hallux rigidus) in the first metatarsophalangeal joint with or without the presence of mild hallux valgus.

18. The Cartiva instrumentation is used to drill an appropriately sized cavity in the metatarsal head and deploy the Cartiva implant into the prepared cavity. Defendants allege joint resurfacing with a Cartiva implant is simple, does not require significant removal of healthy tissue, and typically results in nominal surgical trauma and rapid recovery.[2]

[2] Id.

19. Cartilage is a specialized tissue responsible for mediating contact between bones on surfaces with relative movement. Since cartilage is not vascularized, chondrocytes depend mainly on anaerobic metabolism and get their nutrients through diffusion from the synovial fluid into the matrix.

20. Cartilage does not restore itself or recover quickly from injury- e.g. the complete turnover of the human femoral head cartilage would take approximately 400 years.[3] Joint replacement with a polyvinyl alcohol-based hydrogels (PVA), such as the one used in Cartiva is a joint replacement alternative to traditional fusion treatment.

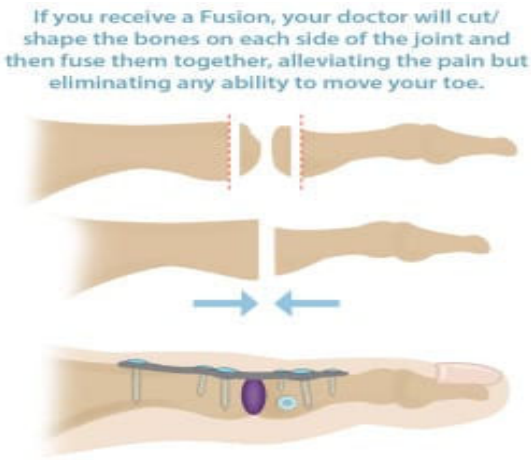
21. The biomechanical design of these implants relies on "hard-on-hard" and "hard-on-soft" interactions. This type of design does not mimic the soft-on-soft interactions that occur in natural cartilage.

22. PVA is biocompatible and has good swelling properties.[4] But the characteristics of the resulting hydrogel could also be tailored by adjusting the production method or by combining PVA with other materials to produce a more suitable and stable material than the current design.[5]

B. Fusion Treatment Option

23. In contrast to Cartiva, an arthrodesis (hereinafter "fusion" is a procedure where the phalangeal and metatarsal bones are cut and shaped to fit (fuse) together to relieve toe joint pain.

[3] Maroudas a. Physicochemical properties of cartilage in the light of ion exchange theory. Biophys J. 1968;8(5):575-595. doi:10.1016/S0006-3495(68)86509-9
[4] Id.
[5] Id. Ma R, Xiong D, Miao F, Zhang J, Peng Y. Novel PVP/PVA hydrogels for articular cartilage replacement. *Mater Sci Eng C*. 2009;29(6):1979-1983. doi:10.1016/j.msec.2009.03.010; Fathi E, Atyabi N, Imani M, Alinejad Z. Physically crosslinked polyvinyl alcohol-dextran blend xerogels: Morphology and thermal behavior. *Carbohydr Polym*. 2011;84(1):145-152. doi:10.1016/j.carbpol.2010.11.018



24. The two bones are then aligned, set at a predetermined angle and permanently fixed with either screws and/or a plate so the two bones "fuse" together permanently. A typical fusion procedure eliminates the ability to move the big toe but eliminates the patient's pain.

C. Medical Facts-Injury

25. Plaintiff files the instant suit against Defendants seeking compensation for injuries and damages Plaintiff sustained as a result of the implantation of the Defective Device into Plaintiff.

26. On or about November 10, 2017, Plaintiff underwent an implantation of Defendants' Defective Device at The William B. Mulherin Surgery Center in Athens, Georgia with Joseph Johnson, M.D.

27. The Cartiva implant surgical procedure has not been effective at alleviating pain or restoring range of motion.

28. At all times material hereto, the Cartiva implant device used in Plaintiff's surgery was designed, manufactured, marketed, retailed, distributed, and/or supplied by Defendants.

29. In addition to a loss of range of motion of the great toe, Plaintiff experienced loss of mobility, nerve damage and debilitating pain of the Right great toe, along with constant irritation and discomfort in the location of the artificial Cartiva device.

30. As a result of the implantation of the Defective Devices, Plaintiff has suffered additional medical expenses for removal of the implant and her Reference total toe implant with bone void filler of the right great toe with burial of the midline right dorsal nerve to correct the toe deformity and bone loss caused by the defective devices, as well as additional loss of income, and pain and suffering.

31. Defendants obtained PMA approval for Cartiva as a Class III device, yet the approval was largely based on the "substantial equivalence" of the Cartiva implant performing similarly to the gold standard treatment of arthrodesis (hereinafter "fusion"). Substantial equivalence is generally used for Class II medical devices and evades a full FDA safety review.

32. The pivotal clinical study (the "Motion" Study)[6] compared the Cartiva implant to the traditional gold standard fusion treatment. The study was a non-inferiority clinical study of 202 subjects treated at 12 sites in the United Kingdom and Canada. The "Motion Study", put simply, is a comparison to a fusion procedure. However, the results of the Motion Study have not been replicated in clinical practice and the Cartiva failure rate is much higher.[7]

D. Insurance Carriers Consider Cartiva Experimental

33. Defendants have a duty to be truthful about the risks of their products in marketing and promotion of the product. Yet, Defendants have suppressed medical industry knowledge from the FDA and public that Cartiva implants have a high failure rate due to migration of the implant caused by implant shrinkage.

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[6]Baumhauer JF, Singh D, Glazebrook M, Blundell C, De Vries G, Le IL, Nielsen D, Pedersen ME, Sakellariou A, Solan M, Wansbrough G, Younger AS, Daniels T; for and on behalf of the CARTIVA Motion Study Group. Prospective, Randomized, Multi-centered Clinical Trial Assessing Safety and Efficacy of a Synthetic Cartilage Implant Versus First Metatarsophalangeal Arthrodesis in Advanced Hallux Rigidus. Foot Ankle Int. 2016 May;37(5):457-69. doi: 10.1177/1071100716635560. Epub 2016 Feb 27. PMID: 26922669.

[7]https://www.medtechdive.com/news/wright-medical-shares-tumble-amid-report-of-cartiva-slowdown/558132/

34. The Motion Study has been widely criticized by industry experts because of its insufficient sample size prompting Cigna to deem the use of the Cartiva implant to treat big toe arthritis "experimental" based upon the lack of sufficient scientific evidence to support the successful treatment claims made by Defendants.[8]

35. In support of its position, Cigna cited the Hayes study which found individual outcome measures are inconsistent and some suggest better outcomes with arthrodesis ("fusion procedure"). The body of evidence is limited by the publication of one "Motion" study within which results were conflicting and did not demonstrate a clear benefit of the Cartiva implant over the gold standard fusion surgery. The Hayes report concluded that a very-low-quality body of evidence is insufficient to draw conclusions regarding the effectiveness and safety of Cartiva implant for treatment of first MTP joint arthritis. Substantial uncertainty exists due to a single identified trial, inconsistencies within the individual study results, and lack of long-term comparative effectiveness data. Large studies assessing the comparative effectiveness and safety of the Cartiva implant are needed.

36. Defendants' original study, Baumhauer et al. (2016) ("aka the Motion Study") reported on a prospective, randomized non-inferiority study to compare the efficacy and safety of the Cartiva implant to great toe fusion surgery for advanced-stage hallux rigidus. The study included 152 implant and 50 arthrodesis patients. The three primary study outcomes assessed were pain, function, and safety. There were no cases of implant fragmentation, wear, or bone loss. This study is the basis of the PMA approval for the Cartiva implant.

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[8] **Partial or total replacement of the first MTP joint or any other foot joint using ANY of the following is considered experimental, investigational or unproven:** Page 2 of 12 Medical Coverage Policy: 0446
• _ceramic implant (e.g., Moje prosthesis [Orthosonics, Ltd., Devon UK])
• _synthetic cartilage implant (e.g., Cartiva Synthetic Cartilage Implant)

37. Cigna also recognized that clinical practice guidelines suggest a different implant design is recommended which renders the Cartiva implant unreasonably dangerous by design. Clinical practice guidelines published by the First Metatarsophalangeal Joint Disorders Panel of the American College of Foot and Ankle Surgeons in 2003 states that interposition arthroplasty with double-stem silicone hinged implants is still a useful procedure for the end-state arthrosis of hallux, and *that titanium grommets are recommended* to minimize ectopic bone formation and protect the implant from the adjacent bone. In addressing total joint systems, the guideline states that numerous implant systems have been developed during the years and several are still used clinically, although long-term clinical usefulness has yet to be established. Judicious use and strict criteria are recommended to avoid complications and problematic revisions (Vanore, et al., 2003).

38. Outside the U.S., NICE published Interventional Procedure Guidance in 2005 based on analysis of seven case series: Hanyu et al. (2001); Sharnkar, et al., (1991); Cracchiolo et al., (1992); Granberry et al., (1991); Bommireddy et al., (2003); Ibrihim et al., (2004); and Malviya et al., (2004). The guidance also states there is little evidence on the durability of newer implants, and that complications may necessitate removal of the joint. These complications include persistent pain, infection, implant loosening, implant fracture, osteolysis, bone over-production, cyst formation, silastic granulomas and transfer metatarsalgia.

E. Defendants Suppressed Adverse Data and Information from FDA/Medical Providers

39. On information and belief, the Defendants had knowledge at all relevant times of the clinical guidelines and outside studies mentioned herein but have suppressed the medical data and information and failed to update the label, failed to update physicians and failed to voluntarily recall the defective device.

40. A follow up to the "Motion Study", Baumhauer et al. (2017) ("Motion II Study"), a study funded by Defendants, retrospectively evaluated the Motion study I (Baumhauer, et al., 2016) finding identical success rates between fusion surgery and the Cartiva implant. These success rates do not exist in clinical practice. Actual patient results have reported failure rates of 64% as opposed to the 13.5% failure rate Defendants reported to the FDA[9].

41. One of the conditions of approval required a PAS (post-approval study) that demonstrates no greater than 13.5% complication rate and tracking the number of patients that were converted to arthrodesis (a/k/a fusion) surgery.

42. On July 12, 2019 the FDA approved Defendants' updated label based upon the findings of the Post-Approval Motion Study to include implant subsidence. However, Defendants incorrectly claimed a majority (76%; 13/17) of the Cartiva serious adverse events were for pain. Additionally, Defendants incorrectly stated in the updated label that 9.2% of Cartiva subjects and 12% of fusion subjects had the implant and/or hardware removed during the course of the study. On information and belief, the Defendants have misrepresented the failure rates to the FDA by labeling the adverse event as pain rather than implant subsidence.

43. Prior to the implantation of Plaintiff's Cartiva implant, Defendants were aware of higher than reported loss of toe mobility, pain and high failure rates of the Cartiva implant due to shrinkage including but not limited to over 144 adverse event reports filed with the FDA.

44. Cartiva did not report the Rosas study[10] to the FDA or take any action to recall the Cartiva implant despite the Rosas study findings which confirmed high failure rates due to implant shrinkage coupled with lysis and bone erosion around the implant. Plain radiographs were assessed

[9] Rosas K, Hurley ET, Kennedy JG. Early Failures of Polyvinyl Alcohol Hydrogel Implant for the Treatment of Hallux Rigidus. Foot & Ankle Orthopaedics. October 2020. doi:10.1177/2473011420S00414

[10] Id.

postoperatively at 2, 4, 8 weeks and final follow-up. Of 14 patients who had taken adequate postoperative plain radiographs, implant subsidence ("shrinkage") was observed in 9 patients (64%) at 4 weeks after surgery and 11 patients (79%) at final follow-up. Eight patients (57%) showed radiologic lucency around the implant. Six patients (40%) had erosion of the proximal phalanx of great toe. Six patients (43%) reported no improvement following surgery at final follow up. Three patients required additional surgery, including debridement and fixation of implant using fibrin glue for loosening. Additionally the Rosas study found significant radiologic subsidence with disintegration of bone around the implant, erosion of the proximal phalynx countersurface as well as recorded implant wear and tear– these are significant harbingers for concern in the long term.

45. To date there are 144 adverse event reports in the Maude database with the majority of events attributed to implant loosening. The loosening is likely due to shrinkage of the implant that is well supported by peer-reviewed literature mentioned herein.

46. The Patient Brochure does not list loss of range of motion of the toe, bone lysis, shrinkage of implant, bone erosion or the inability to walk as a known risk of the Cartiva implant. Plaintiff relied upon the representations made to her in the Patient Brochure which formed the basis of her decision to purchase the Cartiva implant.

47. Device migration was underreported as a risk that occurred in 1 out of 152 patients in a two-year clinical study. However, upon information and belief, Defendants' label and patient brochures failed to provide Plaintiff with information relating to the true failure rate due to migration and prevalence of those failures sufficient for her to make an informed decision prior to her surgery.

48. Defendants' label reflects a Cartiva implant failure of 13.5%. However, in view of continual and ongoing reports and studies, the actual rate of failure of the defective Cartiva device is likely 6-7 times higher than Defendants' reported failure rate.

49. Unfortunately, for patients with Cartiva implant failure, many in the medical community believe that loss of toe range of motion is a symptom of shrinkage (aka implant subsidence), which is a precursor to failure. By any account, the number of Cartiva implant failures is not only exponentially greater than Defendants will admit but the failure rate is reaching alarming proportions.

50. However, during the time Defendants have marketed, labeled and sold its Cartiva implant to Plaintiff, they knew or should have known that the likelihood of patients experiencing implant shrinkage was significantly higher than they reported, and in fact is higher than any comparable product on the market and that pain and discomfort would be a likely consequence of implant shrinkage and migration.

51. The Cartiva implant was considered to be a revolution in great toe arthritis therapy. It came out with a splash and the original studies to get the implant through FDA approval showed striking results. Bob Baravarian, DPM, FACFAS, was involved in helping launch Cartiva and educating other surgeons on the proper use of the Cartiva SCI. Dr. Baravarian's clinic, University Foot and Ankle Institute began to see failures due to the implant slipping into the bone, a process referred to as subsidence. Dr. Baravarian and his clinic will no longer use Cartiva because the failures of Cartiva implants in clinical practice occur more frequently than the results noted in Cartiva's "Motion Study".

52. Dr. Baravarian is not alone in his findings, a retrospective review of 64 Cartiva SCI procedures by Cedars Sinai Medical Center showed a higher level of patient dissatisfaction with

implant outcomes than was seen in Cartiva's Motion Study clinical trial. In the Cedars Sinai trial 37.5% of the patient underwent revision surgery at average 20.9 months of follow-up. More importantly, the radiographic loss of MTP (great toe) joint space and progression of arthritis were present for all cases studied. MRI revealed bony channel widening and a smaller implant-evidence of subsidence (a/k/a shrinkage) with peri-implant fluid suggesting instability at the implant-bone interface. Persistent edema was observed in soft tissues and bone.

F. Defendants Failed To Issue Voluntary Recall

53. Defendants had the availability of a voluntary recall at their disposal to protect the public from the known shrinkage, migration and bone loss issues associated with Cartiva implants. Instead Defendants suppressed Cartiva implant failure information by taking over the sale of the defective device when distributors and physicians decreased the sale and use of the Cartiva implant.

54. A Recall is a voluntary action that takes place because manufacturers and distributors carry out their responsibility to protect the public health and well-being from products that present a risk of injury or gross deception or are otherwise defective. These sections also recognize that recall is an alternative to a Food and Drug Administration-initiated court action for removing or correcting violative, distributed products by setting forth specific recall procedures for the Food and Drug Administration to monitor recalls and assess the adequacy of a firm's efforts in recall." 21 CFR §7.40(a).

55. The Defendants continued to market and sell a defective device that they knew should have been voluntarily recalled, in violation of federal regulations including making an adulterated device that proximately and directly caused Plaintiff's injuries and damages.

G. Degradation Of Cartiva (PVA Gel Implant)

56. The Cartiva implant is a Polyvinyl membrane (PVA) gel implant. Cartiva implants have had degradation of the PVA membrane noted in the Rosas study with findings of loosening, marring and deformity of implant.

57. Upon information and belief, Plaintiff's Cartiva implant had loosening of the implant due to shrinkage, marring and deformity of the implant caused by PVA degradation which directly and proximately caused implant failure, subsequent fusion surgery, pain, loss of mobility and bone loss.

58. The PVA degradation is not an anticipated or intended outcome of the manufacture of the Cartiva implant.

59. The PVA degradation is a mechanical defect that rendered the Cartiva implant inserted in the Plaintiff unreasonably dangerous.

60. The importance of *swelling behavior* is connected to the mechanical and tribological properties of the Cartiva SCI hydrogel, as well as how swelling behavior impacts the risk of implant failure. In 2007, PVA hydrogels were used for treatment of knee cartilage defects in adult rabbits. Results revealed growth over the implant and implant shrinkage.[11] Gels can react to osmotic gradients and swell and *de-swell* accordingly, even in hydrated conditions. This volume change may induce detachment from the tissue or implant and interfacial debonding.[12]

[11] Maher SA, Doty SB, Torzilli PA, et al. Nondegradable hydrogels for the treatment of focal cartilage defects. *J Biomed Mater Res - Part A*. 2007;83(1):145-155. doi:10.1002/jbm.a.31255

[12] Carolina Borges, Rogério Colaço & Ana Paula Serro (2019) Poly(vinyl alcohol)-based hydrogels for joint prosthesis,Annals of Medicine, 51:sup1, 105, DOI: 10.1080/07853890.2018.1562711

61. Since Cartiva implants are composed of PVA which is soluble in water, crosslinking is a crucial step for PVA gel formation. Without a stable structure, the gel is not able to withstand the swelling pressure upon fluid intake and may dissolve.[13]

62. Cartiva is a proprietary PVA-based hydrogel, and its production consists of successive freeze-thawing cycles.

63. The Cartiva implant is a PVA based hydrogel. PVA hydrogels are problematic because the method of manufacturing may result in 1) air bubbles, 2) PVA clumping, 3) fragility of the PVA hydrogel, 4) improper binding of crystallites, 5) disintegration and 6) striation.

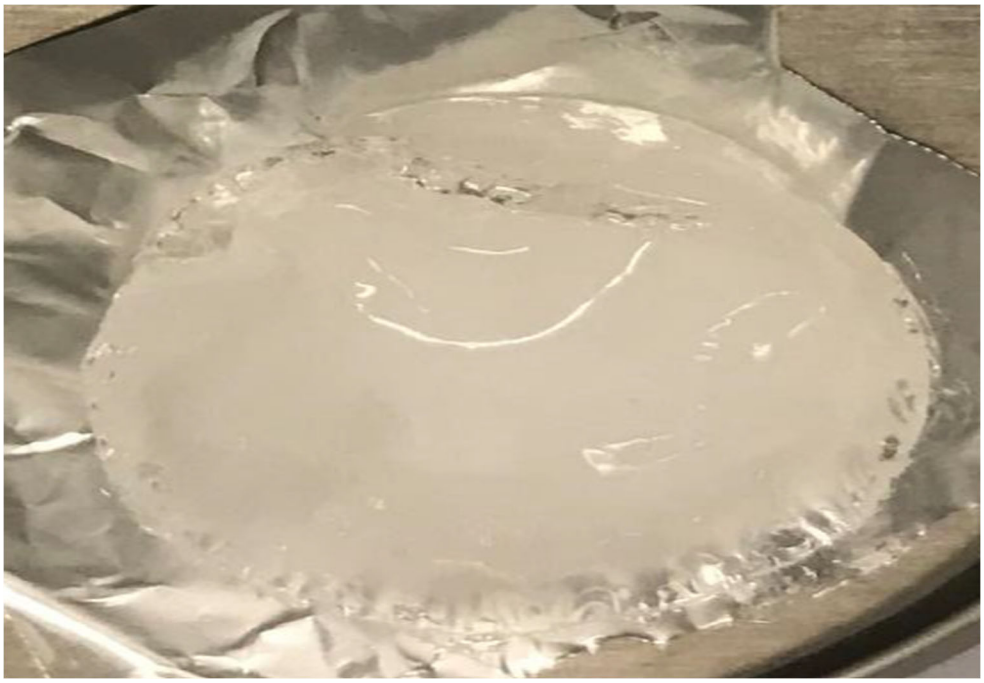

Figure 1-Partially disintegrated Freeze Thawed PVA gel

[13] Peppas NA. Hydrogels in Medicine and Pharmacy. Boca Raton: CRC Press; 1989

Figure 2: Striations on gel caused by rapid cooling and oxygenation of pre gel solution.

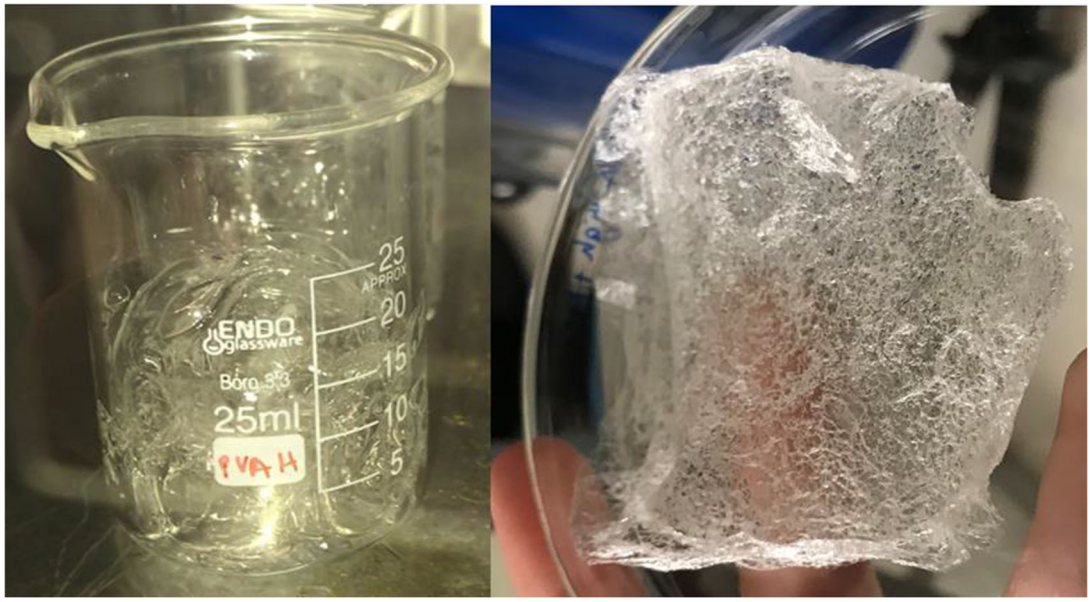

Figure 3: Effects of vacuum on gelation of PVA cause air bubbles to be trapped inside hydrogel.

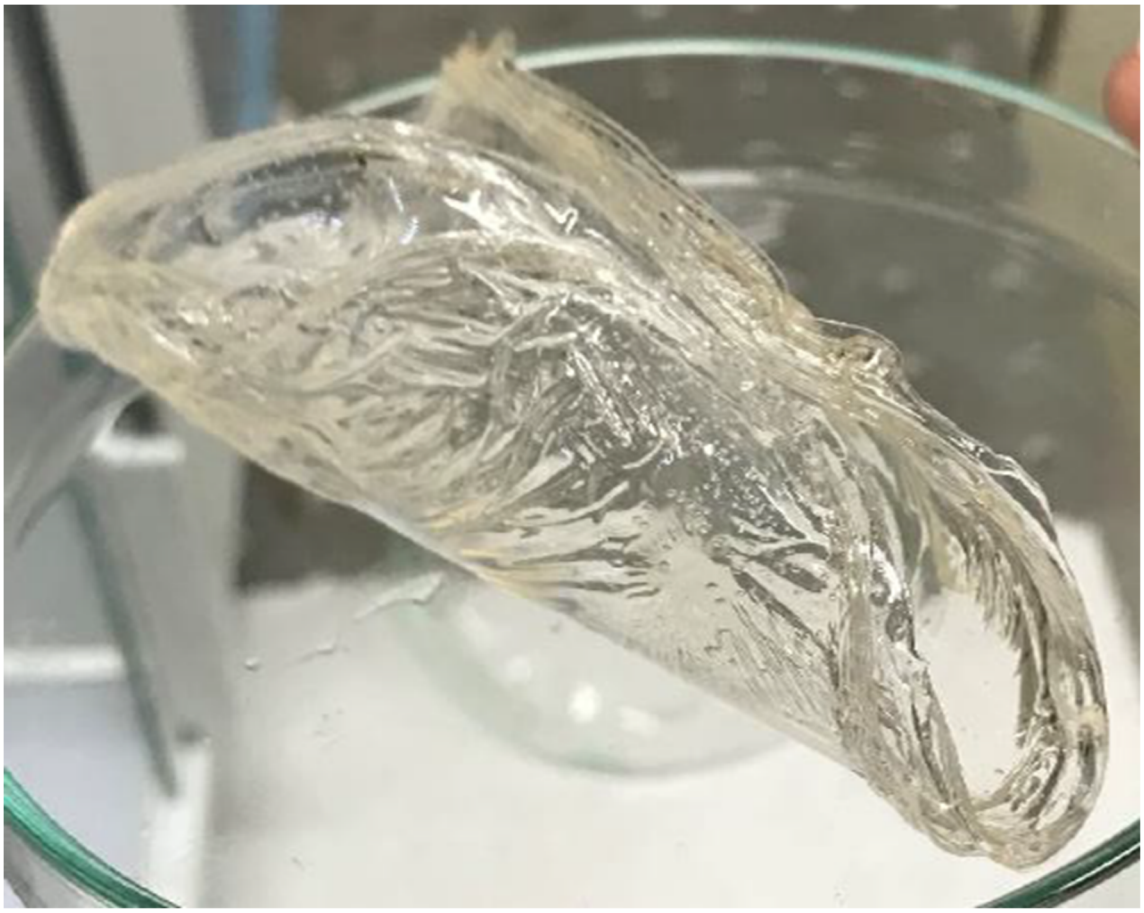

Figure 4: Semi-irreversible contracture of thick PVA hydrogel

64. Manufacturing methods are more problematic for thicker gels like the Cartiva implant. Thicker gels are prone to a lot more variation, and small tweaks in temperature and aeration can contribute to these variations. Consistent temperature and aerations are much harder to produce on a larger scale in a manufacturing environment.

65. The violations of federal regulations, including but not limited to making an adulterated device because the manufacture of the defective device failed to meet established performance standards, or if the methods, facilities or controls used for its manufacture, packing, storage or installation are not in conformity with federal requirements proximately and directly caused Plaintiff's injuries and damages. See 21. U.S.C. §351.

H. Product Representations

66. Defendants' label and patient brochure failed to provide accurate substantive or quantitative prevalence rates of failure or other adverse effects to Plaintiff prior to her surgery.

67. Defendants have represented in patient marketing literature that Cartiva is a quick 35-minute procedure where your physician replaces the damaged cartilage in your big toe with a new synthetic cartilage that behaves like the natural cartilage of your big toe joint.

68. Defendants additionally tell patients, including Plaintiff that "movement matters" further stating in marketing materials - "Your big toe joint is uniquely designed for movement and provides most of the force needed for walking and running. Unlike fusion surgery, which locks the joint in place, CARTIVA Synthetic Cartilage Implant (SCI) reduces pain while also allowing your joint to move how it's supposed to".

69. In addition to promises about the increased toe mobility and function, Defendants allege in marketing that the Cartiva implant is proven to provide long-term pain reduction and increased foot mobility, with 97% reduction in pain demonstrated at almost six years post-procedure. These statements exceed the scope of the FDA approved label.

70. Plaintiff was induced to purchase a Cartiva implant based on the Defendants representations about the safety and efficacy of the product. Furthermore, Plaintiff has endured medical expenses, loss of income, and pain and suffering based upon her reliance of Defendants product representations and will continue to have future expenses to repair the bodily harm caused by the defective Cartiva implant.

71. Defendants' labeling was false and/or misleading. Defendants violated the federal regulations in the labeling of Plaintiff's Cartiva implant thereby causing a misbranded medical device to be ultimately implanted into Plaintiff's body.

72. The conditional approval letter relating to the Cartiva implant stated: "CDRH does not evaluate information related to contract liability warranties, however you should be aware that any such warranty statements must be truthful, accurate, and not misleading, and must be consistent with applicable Federal and State laws".

73. Failure to comply with the conditions of approval invalidates this approval order.

74. Commercial distribution of a device that is not in compliance with these conditions is a violation of the Food, Drug and Cosmetic Act. 21 U.S.C. §§ 301 et seq.

75. Defendants violated the conditional approval requirements and consequently the federal regulations in, among other things, making untrue, inaccurate and/or misleading statements regarding Plaintiff's Cartiva implant. If Defendants had not made these statements and violated the requirements and regulations, Plaintiff would have chosen an alternative treatment option or a different device for implantation into her body.

I. Defendants Failed to Comply with PMA-Post-Approval Surveillance Study

76. The PMA approval order of the Cartiva implant required Defendants collect data to assess the following primary and secondary study endpoints:

a. **Primary Study Endpoints**- The primary endpoint will evaluate the long-term safety of the Cartiva implant by demonstrating the following:

i. Durability of the implant over the longer term.

ii. Assessment of no unanticipated safety concerns that arise after Month 24 up to 5 years.

Addressed by:

1. determining the incidence of serious device-related adverse events per year and overall from Month 24 to Year 5; and

2. summarizing device-related radiographic major complications over time from Month 24 to Year 5.

b. Provide the following **secondary endpoints**:

i. Evaluation of maintenance of range of motion;

ii. Wear characteristics or device degradation for any Cartiva implant removed;

iii. Pain and function over time (Visual Analog Scale [VAS] pain scores, Foot and Ankle Ability Measure [FAAM] Activities of Daily Living [ADL] function scores and FAAMSports function scores); and

iv. Evaluation of radiographic findings (radiolucency, bony reactions, and heterotopic ossification) looking at presence or progression from 24 months to 5+ years as well as correlation with the 5+ years clinical outcomes (effectiveness and safety).

77. In addition to not following the PMA post-approval orders, Defendants have largely ignored these endpoints the FDA placed in the PMA to protect the public safety. The safety data the FDA established did not narrow the Defendants' focus to the Motion study participants. Yet, Defendants have violated the FDA's PMA order by not assessing the safety of each endpoint for each device with reported adverse events, including the Plaintiff's defective device.

78. The lack of safety surveillance served to suppress information from the FDA in violation of the PMA order and the lack of safety surveillance makes the product unreasonably dangerous to end consumers, including Plaintiff.

79. Defendants failed to develop practices and procedures to assure compliance with 21 C.F. R. §814 concerning device modifications, instructions for use, pre-market approval

conditions; and to comply with 21 C.F.R. §§803, 806 and 820, concerning maintaining MDRs, implementing device Removals and Corrections and establishing Quality Systems.

80. Defendants failed to develop practices and procedures to assure compliance with the federal requirements for reporting adverse events, or MDRs, in accordance with 21 U.S.C. §360.

81. Despite the obligations described above, and the obligations of every medical device manufacturer to comply with federal law, Defendants failed to meet numerous federal requirements in their manufacture and sale of the Cartiva implant prior to Plaintiff's surgery and implantation of her Cartiva device which caused him to have implanted a defective and adulterated device causing her injuries and damages

82. Defendants' failure to meet the specific federal requirements outlined above which are applicable to Plaintiff's Cartiva implant, directly and proximately caused Plaintiff's Cartiva implant to be defective, and proximately caused harm and injury to Plaintiff.

83. The causes of action set forth in this first amended complaint are not preempted by § 360k, because the violations alleged are all based on an exclusively federal statutory and regulatory standard of care which includes no "requirement, which is different from, or in addition to, any requirement applicable under" the Food, Drug and Cosmetic Act and regulations promulgated thereunder. As such, the claims set forth in this cause of action contain requirements that are parallel to the Food, Drug and Cosmetic Act and regulations promulgated thereunder.

J. Defendants' Corporate Facts

84. Prior to obtaining FDA approval, Cartiva Inc, raised revenue on July 24, 2013 with an equity funding by offering a round of Regulation D security offerings totaling Four Million Three Hundred Twelve Thousand and Seven Hundred Twelve Dollars ($4,312,712.00).

85. Three years later on July 1, 2016 Cartiva, Inc. obtained premarket approval of the Cartiva SCI.[14]

86. On or about October 10, 2018, Wright Medical Group purchased Cartiva, Inc. for Four Hundred Thirty-Five Million Dollars ($435,000,000).[15] Stock analysts considered it a hefty price tag but also were impressed with strong early adoption of Cartiva SCI, which offers an alternative to fusion surgery which is the gold standard for treating severe arthritis in the big toe.[16]

87. Despite the initial excitement at product launch, stock analysts quickly caught wind of the reports of Cartiva implant failure. By July 2019, RBC stock analysts found some surgeons were implanting fewer of the devices or they had even stopped offering the treatment altogether. Problems with post-operative pain, degree of motion, or the device slipping into the bone in a process known as subsidence ("shrinkage") were reported.[17] Doctors have been unable to replicate the positive results of the company's Motion clinical trial in the broader patient population and have stopped implanting the device or are more cautious about using it. Despite analyst concerns that physicians were dropping offering Cartiva SCI to patients due to failed implants, Wright Medical Group CEO Bob Palmisano remained upbeat on prospects for Cartiva. On the company's earnings call in May 2019, Palmisano said sales growth for the device was exceeding expectations, and he identified the market for treatment of big toe arthritis as a $400 million opportunity.[18]

88. The failure rates of Cartiva SCI was much higher in clinical practice than reported in the Motion Study. Wright Medical Group CEO Bob Palmisano confirmed Cartiva sales in the

[14] PMA # P150017

[15] https://www.globenewswire.com/news-release/2018/10/10/1619047/0/en/Wright-Medical-Group-N-V-Completes-Acquisition-of-Cartiva-Inc.html

[16] https://www.medtechdive.com/news/wright-medical-shares-tumble-amid-report-of-cartiva-slowdown/558132/

[17] Id.

[18] Id.

second quarter second quarter of 2019 fell short of Wright's expectations while touting Wright still maintained gross profit margins of 79%.[19] Palmisano further commented,

> "The unexpected weakness in our U.S. lower extremities business was due to a combination of factors, including the significant reduction in sales by the Cartiva distributors and disappointing performance in our core foot products driven by a higher-than-normal level of sales rep turnover that occurred in a concentrated period of time mid-quarter. To address this, we acted quickly and terminated the Cartiva distributors, and as of August 1, the U.S. Cartiva business has been transitioned to our direct U.S. lower extremities sales force. **We also adjusted the sales compensation program for our entire U.S. lower extremities sales team and are increasing the size of the sales force and aggressively adding experienced reps. We are confident that the actions we have taken will improve the growth rates of Cartiva** and the whole U.S. lower extremities business; however it will take some time for the benefits of these actions to be evident in the sales results, and we believe our updated guidance takes that timing appropriately into account."

89. Stryker, B.V. a wholly owned subsidiary of Stryker purchased Wright Medical Group on or about November 11, 2020 for Four Billion Seven Hundred Thousand Dollars ($4,700,000,000.00).[20]

90. The basis of the "Motion Study" that helped Cartiva gain FDA approval was premised upon a claim that there was a less than 10% failure of the Cartiva implant group that would require subsequent conversion to fusion surgery within the first two years of the implant.[21]

91. The Defendants alleged the Cartiva implant was determined to be statistically equivalent to arthrodesis (fusion surgery) but with the added benefit of greater mobility and less surgical downtime.

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[19] https://www.globenewswire.com/en/news-release/2019/08/07/1898695/33314/en/Wright-Medical-Group-N-V-Reports-2019-Second-Quarter-Financial-Results.html

[20] https://investors.stryker.com/press-releases/news-details/2020/Stryker-completes-acquisition-of-Wright-Medical/default.aspx

[21] Baumhauer JF, Singh D, Glazebrook M, Blundell C, De Vries G, Le IL, Nielsen D, Pedersen ME, Sakellariou A, Solan M, Wansbrough G, Younger AS, Daniels T; for and on behalf of the CARTIVA Motion Study Group. Prospective, Randomized, Multi-centered Clinical Trial Assessing Safety and Efficacy of a Synthetic Cartilage Implant Versus First Metatarsophalangeal Arthrodesis in Advanced Hallux Rigidus. Foot Ankle Int. 2016 May;37(5):457-69. doi: 10.1177/1071100716635560. Epub 2016 Feb 27. PMID: 26922669.

92. Initial results for the Cartiva implant were encouraging, however, unbiased reviewers adopted the position that more independent, non-industry funded research is necessary with larger cohorts to identify implant survivalship and long-term efficacy[22] - something the FDA had already required the Defendants to do in the PMA approval order.

93. Since 2016 Defendant, Stryker f/k/a Cartiva has manufactured, introduced and/or delivered the Cartiva SCI into the stream of interstate commerce in clear violation of the PMA order issued by the FDA.

94. Before commercially distributing the Cartiva SCI in the United States, federal law required Defendant, Stryker f/k/a Cartiva, Inc to submit an application for premarket approval ("PMA") of the device to the Secretary of Health and Human Services. On July 1, 2016, the Food and Drug Administration ("FDA") completed its review of Defendant, Cartiva, Inc.'s PMA application for the Cartiva implant.

95. Based on the materials submitted by Defendant, Stryker f/k/a Cartiva, the FDA conditionally approved the Cartiva implant for commercial distribution.[23] The conditional approval letter from the FDA stated that "[c]ommercial distribution of a device that is not in compliance with these conditions is a violation of the [Food, Drug and Cosmetic] act, [21 U.S.C. §§301, et seq.]."

III. PLAINTIFF'S CARTIVA IMPLANT

96. On or about November 11, 2017, Plaintiff underwent insertion of a Cartiva implant at The William B. Mullherin Surgery Center in Athens, Georgia. At the time of said surgery, Dr.

[22] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7067982/pdf/main.pdf

[23] PMA # P150017

Joseph Johnson utilized and implanted the Defendants' Cartiva SCI instrumentation and implant. Specifically, the following components of said system were utilized:

a. Placer

b. Placement Guide Pin

c. Introducer

d. Metatarsal Drill Bit

e. Cartiva Implant

97. This surgical procedure has not been effective at alleviating pain or restoring range of motion.

98. As a result of the implantation of the Defective Devices, Plaintiff has suffered additional medical expenses for removal of the implant on June 10, 2019 undergoing a Reference total toe implant with bone void filler of the right great toe with burial of the midline right dorsal nerve to correct the toe deformity and bone loss caused by the defective devices, as well as pain and suffering.

IV. DELAYED DISCOVERY

99. Plaintiff repeats and incorporates by reference all prior paragraphs as though fully set forth herein.

100. Plaintiff pleads that the discovery rule should be applied to toll the running of the statute of limitations until Plaintiff knew, or through the exercise of reasonable care and diligence should have known, of facts indicating that the Plaintiff had been injured, the cause of the injury and the tortuous nature of the wrongdoing that caused the injury.

101. Plaintiff's discovery of Cartiva defects is premised on Defendants communications with physicians, sales representatives and/or distributors and the FDA that failures of a successful Cartiva implant were due to surgical technique and not the implant.

102. Despite diligent investigation by Plaintiff into the cause of her injuries, including consultations with Plaintiff's medical providers, the nature of Plaintiff's injuries and damages and their relation to the Plaintiff's Cartiva and Defendants' wrongful conduct was delayed and could not have been discovered, until a date within the applicable statute of limitations for filing each of Plaintiff's claims.

103. Any applicable statutes of limitations have been tolled by the knowing and active concealment and denial of material facts known by the Defendants when they had a duty to disclose those facts. The Defendants' purposeful and fraudulent acts of concealment have kept Plaintiff ignorant of vital information essential to the pursuit of Plaintiff's claims, without any fault or lack of diligence on Plaintiff's part, for the purpose of obtaining delay on Plaintiff's filing of their causes of action. The Defendants' fraudulent concealment did result in such delay.

104. Defendants' are estopped from relying on the statute of limitations defense because Defendants failed to timely disclose, among other things, facts evidencing the defective and unreasonably dangerous nature of their Cartiva implants.

COUNT I
NEGLIGENCE -DESIGN, MANUFACTURE, MISBRANDED AND IMPROPER TRANSFER OF 510K/PMA WITHOUT FDA APPROVAL

105. Plaintiff repeats, reiterates and re-alleges each and every allegation of this Complaint in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

106. Plaintiff is in the class of persons that Defendants should reasonably foresee as being subject to the harm caused by defectively designed Cartiva implants insofar as Plaintiff was the type of person for whom Cartiva implant was intended to be used.

107. At all times herein mentioned, Defendants created, designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and/or distributed its Cartiva implant as hereinabove described that was used by the Plaintiff.

108. Defendants could reasonably have foreseen that its Cartiva were expected to and did reach the usual consumers, handlers, and persons coming into contact with said product without substantial change in the condition in which they were produced, manufactured, sold, distributed and marketed by Defendants.

109. The Cartiva implant inserted into Plaintiff on November 10, 2017 was a class III device while the instruments used to insert Cartiva implants are all Class II devices designed and/or manufactured by Defendants and placed into the interstate stream of commerce.

110. Defendants marketed, distributed and/or permitted use of its Cartiva implants in violation of the Act and regulations promulgated to it.

111. It was the duty of Defendants to comply with the Act, and the regulations promulgated pursuant to it, yet, notwithstanding this duty, Defendants violated the Act in one or more of the following ways:

a. Failed to accurately establish the in vivo life expectancy of the Cartiva, in violation of 21 C.F.R. 820.30(f);

b. Failed to accurately validate the anticipated wear of the Cartiva SCI prior to its release into commercial distribution, in violation of 21 C.F.R. 820.30(g)and the PMA approval order for Cartiva;

c. Failed to establish and maintain appropriate reliability assurance testing to validate the Cartiva SCI design both before and after its entry into the marketplace, in violation of 21 C.F.R. 820.30 (g) and the PMA approval order for Cartiva;

d. Failed to conduct adequate bio-compatibility studies to determine the Cartiva SCI's latent propensity to loosen, migrate into bone and failure to integrate into the joint space as required by the PMA approval order for Cartiva;

e. Failed to identify the component discrepancy, in violation of 21 C.F.R. 820.80(c);

f. Failed to capture the component discrepancy or defect during their Final Acceptance Activities, in violation of 21 C.F.R. 820.80(d) and as required by the PMA approval for Cartiva;

g. Failed to establish and maintain procedures for implementing corrective and preventative action in response to, inter alia, complaints regarding the Cartiva SCI, returned Cartiva SCI, and other quality problems associated with the Cartiva SCI, in violation of 21 C.F.R. 820.100 and the PMA approval order for Cartiva;

h. Failed to appropriately respond to adverse incident reports that strongly indicated the Cartiva implant was Malfunctioning [as defined in 21 C.F.R. 803.3], or otherwise not responding to its Design Objection Intent, in violation of 21 C.F.R. 820.198 and the PMA approval order for Cartiva;

i. Failed to conduct complete device investigations on returned Cartiva implants and components, in violation of 21 C.F.R. 820.198 and the PMA approval order for Cartiva; and/or

j. Failed to comply with the FDA policies and procedures to transfer ownership of the 510k and/or PMA. Without proper transfer of ownership pursuant to FDA requirements it is

not certain the Cartiva device with current Defendants are within the PMA issued for Cartiva, Inc. which means preemption is a non-issue for an unregulated manufacturer.

112. The Cartiva implant and accompanying instruments has been owned by three corporations: Cartiva, Inc. (2015-2017), Wright Medical Group (2018-2020) and Stryker (2020-present), yet the 510k for instruments and the Cartiva implant is still listed with the FDA as Cartiva, Inc with no PMA Supplement approving new manufacturing sites with ownership changes which implies the FDA has not reviewed or approved ownership of the 510k transfer.

113. **FDA TIMELINE:**

Date	**FDA Action**	**Approval Number**
7/1/16	PMA Approval	P150017
8/25/16	PMA Supplement- Change vendor of foil lidstock used to seal primary packaging of Cartiva SCI device	S001
9/29/16	PMA Supplement-Approval of protocol for ODE lead PMA Post Approval Study	S002
11/1/16	PMA Supplement- Approval of 8- and 20-unit shipping configurations for smaller orders	S003
1/6/17	PMA Supplement- Change is supplier of a component used in manufacture of Cartiva SCI	S004
3/1/17	PMA Supplement/Label Change- Modifications to Surgical implantation Technique Guide	S005
11/9/17	PMA Supplement- Expansion of Manufacturing facility	S006
1/29/18	Cartiva Instruments Reclassified as Class II device	Q180170
8/28/18	PMA Supplement-Approval of manufacturing site for instruments to Arcamed LLC	S007

Date	FDA Action	Approval Number
7/2/18	PMA Supplement- Approval of an alternate raw material provider	S008
7/2/18	PMA Supplement- Add additional clean room for manufacture of Cartiva	S009
7/11/19	PMA Supplement- Approval of addition of 6 mm and 12 mm sizes of Cartiva SCI to the previously approved 8 mm and 10 mm device.	S010
7/12/19	PMA Supplement/Label change based on findings of PAS	S011
3/22/19	PMA Supplement-Approval to add clarifying statement regarding need for irrigation during drilling within Instructions for Use and the Surgical Implantation Technique for Cartiva	S012
2/9/20	PMA Supplement- add manufacturing site at Steris Synergy Health in Saxonburg, PA	S013
11/26/19	PMA Supplement-Expanded release criteria of final finished device to accept those that have a homogenously opaque appearance	S014

114. The FDA does permit 510k transfers with the caveat that two companies may not manufacture the same device under a single 510k clearance. Therefore, if a 510k holder wishes to license the right to manufacture a device but also wishes to continue its own manufacturing activity, the FDAs policy is to require the licensee to obtain a new 510(k) clearance.

115. When the holder of an approved PMA enters into an agreement to permit another firm to manufacture and distribute a device under the licensee's private label, FDA approval may

be obtained by either of two procedures: (i) the PMA holder may submit a supplement to the approved PMA; or (ii) the licensee may submit an original PMA that includes, or includes by authorized reference to the holder's approved PMA, all appropriate information required by 21 C.F.R. § 814.20 (required information for PMA applications). There is no evidence on the FDA medical device database that the Cartiva implant used in Plaintiff was manufactured or marketed with FDA approval for the new owners of Cartiva.

116. As a direct and proximate result of Defendants violations of one or more of these federal statutory and regulatory standards of care, the Cartiva implant was used on the Plaintiff and failed and such failure directly caused and/or contributed to the severe and permanent injuries sustained and endured by Plaintiff, as defined in 21 C.F.R. 803.3. As a direct result, Plaintiff endured pain and suffering, including, but not limited to the scarring and disfigurement, and has required additional and debilitating surgeries and has incurred significant medical expenses in the past and will incur additional medical expenses in the future; physical pain and suffering, both past and future; mental anguish and emotional distress, both past and future, including, but not limited to, annoyance and aggravation.

117. This cause of action is based entirely on the contention that Defendants violated federal safety statutes and regulations. Plaintiff did not bring the underlying action as an implied statutory cause of action, but rather they are pursuing parallel state common law claims based upon Defendants' violations of the applicable federal regulations.

118. Under North Carolina law, Defendants' violations of the aforementioned federal statutes and regulations establish a prima facie case of negligence.

119. Thus, under North Carolina common law, a money damages remedy exists for violation of the Act and regulations promulgated thereunder which results in an unreasonably

dangerous product proximately causing injuries, and there is no need for the North Carolina Legislature to act in order to create such a remedy.

120. The Act contains an express preemption provision, 21 U.S.C. §360(k), which in relevant part states: "no state or political subdivision of a state may establish or continue in effect with respect to a device intended for human use any requirement –(1) which is different from, or in addition to, any requirement applicable under this Act [21 USCS §§301, et seq.] to the device, and (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this Act [21 USCS §§301, et seq.]."The cause of action set forth in this Claim for Relief is not preempted by 21 U.S.C.

121. The cause of action set forth in this Claim for Relief is not preempted by 21 U.S.C. §306(k) because the violations alleged are all based on an exclusively federal statutory and regulatory set of requirements which include no "requirement, which is different from, or in addition to, any requirement applicable under" the Act and regulations promulgated thereunder. As such, the claims set forth herein contain requirements that are parallel to the Act and regulations promulgated thereunder and not preempted.[24]

122. As a direct and proximate result of Defendants aforementioned actions, Plaintiff prays for judgment against Defendants in an amount in excess of Seventy-Five Thousand Dollars ($75,000.00).

123. Defendants created, designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed a defective product which created an unreasonable risk

[24] In Riegel, the Court noted that § 360k "does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations; the state duties in such a case 'parallel,' rather than add to federal requirements." 552 U.S. at 330 (2008)

to the health of consumers and to Plaintiff, in particular, and Defendants are therefore liable for the injuries sustained by the Plaintiff.

COUNT II
MISBRANDED AND ADULTERATED DEVICE

124. Plaintiff repeats, reiterates and re-alleges each and every allegation of this Complaint in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

125. Plaintiff has endured painful surgeries scarring and nerve damage caused by the defective Cartiva implants. The original Cartiva implant was a Class III device and all instruments used to insert the Cartiva implant are Class II devices designed and/or manufactured by Defendants and placed into the interstate stream of commerce.

126. Defendants marketed, distributed and/or permitted use of its Cartiva implant and insertion instruments in violation of the Act and regulations promulgated to it.

127. It was the duty of Defendants to comply with the Act, and the regulations promulgated pursuant to it, yet, notwithstanding this duty, Defendants violated the Act in one or more of the following ways:

a. Failed to submit a PMA supplement to warn of risk of implant shrinkage, migration and bone loss for review and approval as required by the FDA. 21 C.F.R. §814.39 and PMA approval order for Cartiva. Despite Defendants' knowledge of higher failure rates than previously reported to the FDA, Defendants chose to do nothing. It is the Defendants, not the FDA who had a duty to report the failure rates and manufacturing problems to the FDA. The burden for determining whether a supplement is required is primarily on the PMA holder, changes for which an applicant shall submit a PMA supplement include, but are not limited to, the following types of changes if they affect the safety or effectiveness of the device:

i. New indications for use of the device.

ii. Labeling changes.

iii. The use of a different facility or establishment to manufacture, process, or package the device.

iv. Changes in sterilization procedures.

v. Changes in packaging.

vi. Changes in the performance or design specifications, circuits, components, ingredients, principle of operation, or physical layout of the device.

b. Defendants sold, distributed and permitted use of its devices in violation of the regulations prescribed under 21 U.S.C. §360j(e) and 21 U.S.C. § 352(q) which required design validation and manufacturing controls to assure the Defendants would not produce a medical device with impurities or inconsistencies. Defendants also had a duty to provide a label that was truthful about the risks associated with the Cartiva implant and Defendants have failed to do so;

c. Failed to restrict the use of the Cartiva implant and instruments in violation of 21 U.S.C. §352(r) and the PMA approval order for Cartiva. The Cartiva PMA approval order provided the device is further restricted under section 515(d)(1)(B)(ii) of the act insofar as the labeling must specify the specific training or experience practitioners need in order to use the device. In direct violation of the PMA order, Defendants' Direction For Use merely states "The Cartiva SCI device should only be used by experienced surgeons who have undergone training in the use of this device". There is no limitation on the physician experience-specialty type, years of experience nor do the instructions provide any details about the type of training required. The PMA approval order further states the FDA has determined that these restrictions on sale and distribution are necessary to provide reasonable assurance of the safety and effectiveness of the device. Your device is

therefore a restricted device subject to the requirements in sections 502(q) and (r) of the act, in addition to the many other FDA requirements governing the manufacture, distribution, and marketing of devices. As mentioned herein, Defendants had a duty to print on the label and marketing of the Cartiva implant all relevant warnings, precautions, side effects, instructions for use and contraindications and has failed to issue any warnings beyond the generalizations provided in the label; and

d. Failed to comply with the requirements of 21 U.S.C.§ 360i which provides a device manufacturer shall report to the FDA when the manufacturer receives or otherwise becomes aware of information that reasonably suggests that one of its marketed devices may have caused or contributed to a death or serious injury, or has malfunctioned and that such device or a similar device marketed by the manufacturer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur. As mentioned herein, Defendants have knowledge that failure rates are higher than reported to the FDA, yet Defendants have taken no action to protect the public, including Plaintiff from harm caused by the defective Cartiva implant; and

e. Defendants have failed to comply with 21 U.S.C.§ 360l which required Defendants to submit a surveillance plan for its device once commercial distribution began to detect adverse health events to the public. Instead Defendants have relied solely on the Motion Study to continue with commercial distribution ignoring the adverse event reports and other studies correlating findings the failure rate is 6-7 times higher than reported by Defendants.

128. As a direct and proximate result of Defendants' violations of one or more of these federal statutory and regulatory standards of care, Plaintiff had a Cartiva implanted using Cartiva instruments and it failed, and such failure directly caused and/or contributed to the severe and

permanent injuries sustained and endured by Plaintiff as defined in 21 C.F.R. 803.3. As a direct result, Plaintiff endured suffering, including, but not limited to, recurrent dislocations and subluxations with swelling, toe enlargement, and has required additional and debilitating surgeries and has incurred significant medical expenses in the past and will incur additional medical expenses in the future; physical pain and suffering, both past and future; mental anguish and emotional distress, both past and future, including, but not limited to, annoyance and aggravation.

129. This cause of action is based entirely on the contention that Defendants violated federal safety statutes and regulations. Plaintiffs do not bring the underlying action as an implied statutory cause of action, but rather they are pursuing parallel state common law claims based upon Defendants' violations of the applicable federal regulations.

130. Under North Carolina's Product Liability Act, Defendants' violations of the aforementioned federal statutes and regulations establish a prima facie case of products liability that can be asserted in North Carolina: defective design, defective manufacturing, and failure-to-warn. *Driver v. Burlington Aviation, Inc.,* 110 N.C. App. 519, 527, 430 S.E.2d 476, 482 (1993

131. Thus, under North Carolina common law, a money damages remedy exists for violation of the Act and regulations promulgated thereunder which results in an unreasonably dangerous product proximately causing injuries, and there is no need for the North Carolina Legislature to act in order to create such a remedy.

132. The Act contains an express preemption provision, 21 U.S.C. §360(k), which in relevant part states: "no state or political subdivision of a state may establish or continue in effect with respect to a device intended for human use any requirement (1) which is different from, or in addition to, any requirement applicable under this Act [21 USCS §§301, et seq.] to the device, and

(2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this Act [21 USCS §§301, et seq.]."

133. The cause of action set forth in this Claim for Relief is not preempted by 21 U.S.C. §306(k) because the violations alleged are all based on an exclusively federal statutory and regulatory set of requirements which include no "requirement, which is different from, or in addition to, any requirement applicable under" the Act and regulations promulgated thereunder. See; *Bausch v. Stryker*, 630 F.3d 546, 556 (7th Cir. 2010) (claims for negligence and strict products liability relating to a Class III medical device were not expressly preempted by federal law to the extent they were based on the defendants' violations of federal law). As such, the claims set forth herein contain requirements that are parallel to the Act and regulations promulgated thereunder.

134. As a direct and proximate result of Defendants aforementioned actions, Plaintiff, prays for judgment against Defendants in an amount in excess of Seventy-Five Thousand Dollars ($75,000.00).

COUNT III
STATE LAW AND COMMON LAW CLAIMS OF PRODUCT LIABILITY AND NEGLIGENCE FOR CLASS II DEVICES/CLASS III DEVICES

135. Plaintiff repeats, reiterates and re-alleges each and every allegation of this Complaint in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

136. The Cartiva implant and corresponding Cartiva instruments used on Plaintiff on November 1, 2018 was designed, manufactured and distributed by Defendants and placed into the stream of interstate commerce by Defendants. Said components were defective in design and/or manufacture. Said defects existed when the components left the hands of Defendants making the components unreasonably dangerous beyond the contemplation of the ordinary user.

137. Defendants further breached applicable implied and express warranties, including warranties of merchantability and fitness for a particular purpose. Further, Defendants failed to provide appropriate warnings regarding the potential dangers associated with the use of said components, including warnings regarding the risk of migration of Cartiva implant and shrinkage of the Cartiva SCI, such as was experienced by Plaintiff.

138. As a direct and proximate result of the design and/or manufacturing defects, failure to warn and breach of express and implied warranties related to Defendants' Cartiva implant and corresponding instruments designed, manufactured, distributed, sold and/or placed into the stream of commerce by the Defendants, Plaintiff suffered severe and permanent injuries, including, but not limited to, scarring and disfigurement, pain and suffering and has required additional and debilitating surgeries and has incurred significant medical expenses in the past and will incur additional medical expenses in the future; physical pain and suffering, both past and future; mental anguish and emotional distress, both past and future, including, but not limited to, annoyance and aggravation; and has been damaged in an amount in excess of Seventy Five Thousand Dollars ($75,000.00).

139. As a direct and proximate result of the willful, wanton, intentional acts, reckless and/or the willful, wanton, intentional acts, reckless and/or the willful, wanton, intentional and reckless failures to act by Defendants Plaintiffs(s) suffered the aforesaid damages and, as such, Plaintiff(s)s demand that punitive damages be awarded against Defendants.

COUNT IV
BREACH OF EXPRESS WARRANTY

140. Plaintiff repeats, reiterates and re-alleges each and every allegation of this Complaint in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

141. Defendants knew that Cartiva implant had problems, including but not limited to shrinkage and migration out of joint space into the bone. Defendants advertised Cartiva implants as a non-invasive procedure, designed to reduce quickly restore toe mobility with a simple procedure. None of Defendants' advertising, marketing, or informational materials to the Plaintiff, mentioned that Cartiva had the ability to cause a condition that results in a permanent disfigurement to the body that can only be resolved through invasive surgeries resulting in the *opposite effect* of the device's advertised purpose.

142. Plaintiff relied on the skill and judgment of the Defendants that the device was adequately tested and rendered safe to use for its intended purpose.

143. Plaintiff became interested in and underwent the Cartiva implant procedure based on the Defendants' representation about the procedure.

144. Because of the innate defective nature of the Cartiva implant, Plaintiff and the individuals performing the Cartiva implant procedure on Plaintiff, through the use of reasonable care could not have discovered the defective nature of the Cartiva device or its perceived dangers.

145. As the direct and proximate result of Defendants' conduct, Plaintiff sustained serious injuries that were directly caused by the defective, unsafe, and unreasonably dangerous Cartiva implant that could not safely be used for the purpose for which it was marketed, advertised, promoted and intended.

146. As the direct and proximate result of Defendants' wrongful conduct, Plaintiff suffered and continue to suffer economic losses, emotional distress, permanent disfigurement, physical pain, mental anguish, diminished enjoyment of life and future medical expenses.

COUNT V
BREACH OF IMPLIED WARRANTY

147. Plaintiff repeats, reiterates and re-alleges each and every allegation of this Complaint in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

148. At all times herein mentioned, Defendants manufactured, compounded, portrayed, distributed, recommended, merchandized, advertised, promoted and sold its Cartiva implant and instruments.

149. At the time Defendants marketed, sold, and distributed its Cartiva implant and instruments to be used on Plaintiff, Defendants knew of the use for which its Cartiva devices was intended and impliedly warranted the product to be of merchantable quality and safe and fit for such use.

150. Defendants impliedly represented and warranted to the users of its Cartiva devices and/or their physicians, and/or healthcare providers, and/or the FDA that its Cartiva devices were safe and of merchantable quality and fit for the ordinary purpose for which said products were to be used.

151. That said representations and warranties aforementioned were false, misleading, and inaccurate in that its Cartiva devices were unsafe, unreasonably dangerous, improper, not of merchantable quality, and defective.

152. Plaintiff and/or members of the medical community and/or healthcare professionals did rely on said implied warranties of merchantability and fitness for a particular use and purpose.

153. Plaintiff and/or her physicians and/or healthcare professionals reasonably relied upon the skill and judgment of Defendants as to whether its Cartiva devices were of merchantable quality and safe and fit for it intended use.

154. Defendants' Cartiva devices were injected into the stream of commerce by Defendants in a defective, unsafe, and inherently dangerous condition and the products and materials were expected to and did reach users, handlers, and persons coming into contact with said products without substantial change in the condition in which they were sold.

155. Defendants herein breached the aforesaid implied warranties, as its Cartiva devices were neither merchantable nor fit for their intended purposes and uses.

156. By reason of the foregoing Plaintiff has experienced and continues to experience, serious and dangerous side effects including but not limited to, mobility problems and disability, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications.

157. As a result of the foregoing acts and omissions Plaintiff requires and/or will require more health care and services and did incur medical, health, incidental and related expenses. Plaintiff is informed and believes and further alleges that Plaintiff will in the future be required to obtain further medical and/or hospital care, attention, and services.

COUNT VI
FAILURE TO WARN

158. Plaintiff repeats, reiterates and re-alleges each and every allegation of this Complaint in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

159. Defendants are, and at all times mentioned in this Complaint was, engaged in the business of designing, manufacturing, assembling, and selling a medical device product known as Cartiva devices with the purpose of gaining profits from the distribution thereof.

160. Defendants directly or through its agents, apparent agents, servants, or employees designed, manufactured, tested, marketed, and commercially distributed the Cartiva SCI system that was used on Plaintiff.

161. Defendants knew that its Cartiva devices were unreasonably dangerous, unsafe, and/or defective and could cause harm to those who used it, including Plaintiff.

162. Defendants knew that implant migration into the bone was not preventable and is unavoidable if undergoing the Cartiva SCI procedure.

163. Defendants had superior knowledge about implant migration because it was in possession and had access to facts and information about the condition that was not available to anyone else. As the manufacturer of the device, Defendants were a centralized hub of information about the device's adverse effects, including migration. It had received thousands of reports of users developing the condition, had access to those person's medical records and information regarding diagnosis, treatment, and occurrence rate, which it did not disclose to the medical community.

164. Defendants had a duty to provide adequate warnings about implant shrinkage and migration, a dangerous adverse effect of its Cartiva SCI system, to Plaintiff's provider.

165. Defendants failed to provide adequate warnings to Plaintiff's provider because the language used by Defendants to describe risks in its training materials:

a. Inaccurate in content and ambiguous in manner of expression;

b. Did not adequately inform the providers about a condition which is: 1) unfamiliar to the medical community, 2) is only associated with the Cartiva device, and 3) about which Defendants had superior knowledge;

c. Creatively used insufficient and vague language that did not provide enough specificity about the condition, which was necessary for the Cartiva providers to know about the risks of using the device;

d. Misrepresented facts about the adverse effect;

e. Did not use concrete terms like "shrinkage" and "implant migration" to describe the risks;

f. Did not warn that it is likely that multiple surgeries may be necessary to remove and/or correct a failed Cartiva SCI;

g. Did not disclose that Cartiva implant failure can cause permanent nerve damage and deformity.

166. Defendants are liable for Plaintiff's damages because its product was defective due to its failure to adequately warn Cartiva SCI providers about the danger of the Cartiva Implant system.

167. As the direct and proximate result of Defendants' wrongful conduct, Plaintiff suffered and continue to suffer economic losses, emotional distress, permanent disfigurement, physical pain, mental anguish, diminished enjoyment of life and future medical expenses.

COUNT VII
PUNITIVE/EXEMPLARY DAMAGES

168. Plaintiff repeats, reiterates and re-alleges each and every allegation of this Complaint in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

169. Defendants' conduct in deceiving Cartiva system providers and/or convincing providers to participate in the scheme, in not informing Plaintiff of the seriousness, permanency, and frequency of implant shrinkage and migration, in concealing material information regarding

the serious adverse effect of the Cartiva implant, and in creating a system by which consumers did not have fair access to important information about Cartiva, was so reckless or wanting in care that it constituted a conscious disregard or indifference to the life, safety, or rights of persons exposed to such conduct.

170. Defendants, as a corporation, actively and knowingly participated in the dissemination of misrepresentations and concealment of material information related to implant shrinkage and migration and its Cartiva SCI implant system.

171. Defendants and their agent's malicious and fraudulent conduct must be punished to deter future harm to others. Therefore, exemplary damages are appropriate under that the circumstances.

PRAYER FOR RELIEF

Plaintiff incorporates by reference each and every paragraph of this First Amended Complaint as though set forth here in full and further prays:

172. So far as the law and this Court allows, Plaintiff demands judgment against each Defendant on each count as follows:

a. All available compensatory damages for the described losses with respect to each cause of action;

b. Past and future medical expenses, as well as the cost associated with past and future life care;

c. Past and future lost wages and loss of earning capacity;

d. Past and future emotional distress;

e. Consequential damages;

f. All available noneconomic damages, including without limitation pain, suffering, and loss of enjoyment of life;

g. All wrongful death damages permitted by law, where applicable;

h. Disgorgement of profits obtained through unjust enrichment;

i. Restitution;

j. Punitive damages with respect to each cause of action;

k. Reasonable attorneys' fees where recoverable;

l. Costs of this action;

m. Pre-judgment and all other interest recoverable; and

n. Such other additional, further, and general relief as Plaintiff may be entitled to in law or in equity as justice so requires.

DEMAND FOR JURY TRIAL

Plaintiff hereby demands a trial by jury on all issues raised in this Complaint.

Date: May 31, 2022

Respectfully submitted,

/s/ Scott Harris
Scott Harris, Esq.
Milberg Coleman Bryson Phillips Grossman, PLLC
900 W. Morgan Street
Raleigh, NC 27603
Telephone: (919) 600-5000
Fax: (919) 600-5035
sharris@milberg.com
Attorney for Plaintiff